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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,280	10/08/2001	Alex Urich	155696-0034	5788

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,280

Applicant(s)

URICH, ALEX

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,8,9,11,13,14,16,18,19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,8,9,11,13,14,16,18,19 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 11 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Saaski et al., 5,585,011.

As to claims 1 and 11, Saaski et al. discloses a pump (130), and a non-linear flow restrictor (86) coupled to said pump, see Figure 10 or 11, said non-linear flow restrictor has a plurality of bends that change the direction of fluid flow to create a non-linear relationship between a fluid pressure and a fluid flowrate (column 30, lines 38-45.)

As to claim 21, Saaski et al. discloses a method comprising creating a flow of fluid that has a pressure and a flowrate, see column 4, lines 12-39; and restricting the flow of fluid in a tube by changing a direction of fluid flow a plurality of times so that a variation in the pressure will create a non-linear change in the flowrate, see column 30, lines 34-45.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saaski et al., 5,585,011, in view of Nun, 6,217,584.

Saaski discloses the invention substantially as claimed (see above). More specifically, Saaski discloses a non-linear flow restrictor and a pump. Saaski discloses an embodiment wherein the pump is a piezo-electric motor pump (col. 4, lines 29-30), but does not specifically disclose an embodiment wherein the pump is a peristaltic pump. Saaski however states that the described invention is by way of non-limiting example, and that modifications, adaptations and variations apparent to those skilled in the art are within the scope of the disclosure, column 101, lines 4-11.

Nun, similar to Saaski, discloses a fluid handling device (204) connected to a pump (column 12, line 8.) Nun specifically teaches that the pump may be a peristaltic pump to regulate the flow of fluid (column 12, lines 3-8.)

It would have been obvious to one of ordinary skill to substitute the peristaltic pump taught by Nun for the piezo-electric motor pump in the Saaski device since both

pumps are conventional pumps for regulating the flow of fluid, and it is well known in the art that one conventional pumping means can be substituted for another.

3. Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saaski et al., 5,585,011, in view of Cochran et al., 5,910,139.

Saaski discloses the invention substantially as claimed (see above). More specifically, Saaski discloses a non-linear flow restrictor and a pump. Saaski discloses an embodiment wherein the pump is a piezo-electric motor pump (col. 4, lines 29-30.) However, Saaski does not specifically disclose that the pump may be a venturi pump.

Cochran, similar to Saaski, discloses a medical device (col. 17, line 19-24) connected to a pump (col. 17, line 29.) Cochran further discloses that the pump may be a venturi pump (column 17, line 29.)

It would have been obvious to one of ordinary skill to substitute the venturi pump taught by Cochran for the piezo-electric motor pump in the Saaski device since both pumps are conventional pumps for regulating the flow of fluid, and it is well known in the art that one conventional pumping means can be substituted for another.

4. Claims 6, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anis et al., 5,911,699, in view of Saaski et al., 5,585,011.

Anis discloses the invention substantially as claimed.

More specifically, Anis discloses a device comprising:

handpiece (10);

a cutting element (17A) attached to said handpiece;

a pump or pump means (column 6, line 46) coupled to said handpiece.

Anis teaches that the device is used to remove tissue from the body such as for example removal of cataracts from the eye, (col. 1, lines 19-20.) Although Anis discloses that the device includes a pump mechanism for irrigating fluid (col. 6, line 46), Anis does not disclose a non-linear flow restrictor or flow restrictor means coupled to the pump and handpiece, wherein the non-linear flow restrictor has a plurality of bends that change the direction of fluid flow to create a non-linear relationship between a fluid pressure and a fluid.

Saaski teaches a flow regulator that may be used to control the flow rate of a fluid medication (col. 12, lines 52-53.) Saaski discloses that one aspect of the invention is to provide fluid handling devices that are capable of continually handling fluids over an extended period of time at relatively low flow rates (col. 1, lines 36-39.) Saaski also discloses that another aspect of the invention is to provide fluid handling devices which are small (col. 1, lines 42-46.) Saaski further discloses that another aspect of the invention is to provide a fluid handling device in the form of a flow regulator which will maintain the flow of the medication within predetermined parameters, despite fluctuations in the pressure of the medication (col. 2, line 66 – col. 3, line 3.) Saaski does not limit the device to a particular medical device or procedure, but refers to a fluid handling device as it applies to many different medical situations (col. 1, lines 20 and 42; col. 2, lines 10, 44 and 56.) Saaski further states that the described invention is by

way of non-limiting example, and that modifications, adaptations and variations apparent to those skilled in the art are within the scope of the disclosure, column 101, lines 4-11.

Since the Anis apparatus is a fluid handling device with a pump, and Saaski teaches a flow regulator that provides advantages to a fluid handling device with a pump, it would have been obvious to one of ordinary skill in the art to provide the flow regulator taught by Saaski in the Anis invention in order to allow for the Anis pump to continually handle fluids over an extended period of time at low flow rates, or to provide for a fluid handling device that is small, or to maintain the flow of irrigation within predetermined parameters, as taught by Saaski, as would be desirable in the Anis invention in irrigating fluid during surgery.

5. Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anis et al., 5,911,699, in view of Saaski et al., 5,585,011, as applied to claims 6 and 16, and further in view of Nun, 6,217,584.

The invention as claimed is substantially disclosed by Anis in view of Saaski (see above with respect to claims 6 and 16.) More specifically, Saaski discloses a non-linear flow restrictor and a pump. Saaski discloses an embodiment wherein the pump is a piezo-electric motor pump (col. 4, lines 29-30), but does not specifically disclose an embodiment wherein the pump is a peristaltic pump. Saaski however states that the described invention is by way of non-limiting example, and that modifications,

adaptations and variations apparent to those skilled in the art are within the scope of the disclosure, column 101, lines 4-11.

Nun, similar to Saaski and Anis, discloses a fluid handling device (204) connected to a pump (column 12, line 8.) Nun specifically teaches that the pump may be a peristaltic pump to regulate the flow of fluid (column 12, lines 3-8.)

It would have been obvious to one of ordinary skill to substitute the venturi pump taught by Nun for the piezo-electric motor pump in the Saaski device since both pumps are conventional pumps for regulating the flow of fluid, and it is well known in the art that one conventional pumping means can be substituted for another.

6. Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anis et al., 5,911,699, in view of Saaski et al., 5,585,011, as applied to claims 6 and 16, and further in view of Cochran et al., 5,910,139.

The invention as claimed is substantially disclosed by Anis in view of Saaski (see above with respect to claims 6 and 16). More specifically, Saaski discloses a non-linear flow restrictor and a pump. Saaski discloses an embodiment wherein the pump is a piezo-electric motor pump (col. 4, lines 29-30.) However, Saaski does not specifically disclose that the pump may be a venturi pump.

Cochran, similar to Saaski and Anis, discloses a medical device (col. 17, line 19-24) connected to a pump (col. 17, line 29.) Cochran further discloses that the pump may be a venturi pump (column 17, line 29.)

It would have been obvious to one of ordinary skill to substitute the peristaltic pump taught by Cochran for the piezo-electric motor pump in the Saaski device since both pumps are conventional pumps for regulating the flow of fluid, and it is well known in the art that one conventional pumping means can be substituted for another.

Response to Arguments

Applicant's arguments filed March 23, 2004 have been fully considered but they are not persuasive.

Applicant argues on page 4 that Saaski does not disclose or suggest to provide a flow restrictor with enough bends to create a non-linear relationship between pressure and flowrate. Applicant goes on to assert that Saaski discloses a valve with a flexure and that the fluid pressure can push the flexure toward the regulator valve seat to change the height of the regulator gap and that the non-linear relationship is created by varying the height of the regulator gap, not by changing the direction of fluid flow through a series of bends in the restrictor.

In response, Examiner asserts that the fact that a non-linear relationship can be created by the flexure and regulator valve seat does not preclude a non-linear relationship created by changing the direction of fluid flow through a series of bends in the restrictor.

Applicant also argues on page 4 that Saaski is silent as to whether there are enough bends in the configurations of Saaski to actually create a non-linear relationship between pressure and flowrate.

In response, Examiner points to Figures 9, 10 and 11 of Saaski which show examples of non-linear configurations. Figure 10 especially disclose a plurality of bends. Examiner asserts that these bends are capable of creating a non-linear relationship between pressure and flowrate. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Moreover, these bends are no different from the bends described in Applicant's disclosure as being capable of creating a non-linear relationship between pressure and flowrate. For example, page 10, lines 4-8, of Applicant's specification state that "[t]he flow restrictor 50 may include a plurality of bends 52 in an aspiration tube. The bends 52 change the direction of fluid flow and create a non-linear relationship between the flowrate and pressure in the tube 34'." Saaski likewise teaches a tube having bends, wherein there may be multiple bends (see Figure 10 for example) and wherein the tube may be one of various lengths (column 30, 41-45) and various sizes (column 31, 32-36.)

Thus, Saaski teaches a tube having a plurality of bends creating a non-linear relationship between pressure and flowrate.

Applicant also asserts on page 4 that Saaski states that the circular, spiral or serpentine configurations are provided to make the regulator more compact, and that there is no teaching to provide enough bends and corresponding changes in a fluid direction to create a non-linear relationship between pressure and flowrate.

In response, Examiner asserts that the fact that Saaski discloses that the circular, spiral or serpentine configurations serve to make the regulator more compact does not preclude it from creating a non-linear relationship between pressure and flowrate. Examiner reasserts that the Saaski bends create a non-linear relationship between pressure and flowrate as described above.

Conclusion

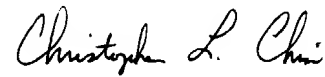
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641

9/22/04